

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Keiichi FUJIWARA et al.
Appln. No.: 10/582,174 Group Art Unit: 1612
Filed: December 7, 2004 Examiner: GIGI HUANG
For: DRUG-CONTAINING GRAINS AND SOLID PREPARATION
CONTAINING THE GRAINS

DECLARATION

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

I, Norihito SHIMONO, a citizen of Japan and residing at No. 3-13, Ibukidainishi-machi 6-chome, Nishi-ku, Kobe-shi, Hyogo, Japan, declare and say as follows.

1. I was graduated from the Kyoto University, Faculty of Pharmacy, Department of Pharmaceutical Sciences, Japan in March 1986, and completed the master's course at the same university, Graduated School of Pharmaceutical Sciences in March 1988, and awarded the degree of Doctor of PH from the Kyoto University, Graduated School of Pharmaceutical Sciences in January 2003.
2. Since April 1988 up till the present, I have been an employee of Dainippon Sumitomo Pharma Company, Limited (former Dainippon Pharmaceutical Company, Limited), and I have been engaged in research work of pharmaceutical formulations for 23 years and now I am handling development management work of Technology Research & Development Division in Medical Product Research Laboratory of said company.
3. I am one of the inventors of the present U.S. Patent Application No. 10/582,174 and am familiar with the present invention.
4. Based upon my knowledge and experience in the drug formulation

fields, I can say as follows.

5. In my previous Declaration signed on November 4, 2010, I showed the surface of the particle examined by means of a Laser Raman microspectroscope. According to the results, the medicament (mosapride citrate) was present on the surface of the particle without coating.

6. When I and co-researchers prepared the particle for the Laser Raman analysis, we tested the particle for evaluating the masking effect of the unpleasant taste. The result is shown below. The evaluation of the masking was the same as Tables 13-15 of the present specification.

Item	Result
Masking degree of the unpleasant taste	◎ (Masking effect was clearly exhibited and the unpleasant taste was not felt at all)

7. In conclusion, it is definite that the unpleasant taste of the present particles is completely masked though the particles are uncoated and the medicament is present on the surface of the particles, from the experimental results described in my previous Declaration and the above result.

8. The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

This 30th day of August, 2011

Norihito Shimono

Norihito SHIMONO, Ph.D.